

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P0998D1

Serial No.

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Cleland et al.Filing Date  
18 Mar 1999Group  
1642

09/27/99  
U.S. PTO  
JUL 35 1999  
03/18/99

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
<i>89</i>	* 1	08/508,014		Fick et al.			27.07.95
	* 2	4,093,606	06.06.78	Coval, M.			
	* 3	4,499,073	12.02.85	Tenold, R.			
	* 4	4,877,608	31.10.89	Lee, T. et al.			
	* 5	4,940,782	10.07.90	Rup et al.			08.06.87
	* 6	5,032,405	16.07.91	Huang, H. et al.			
	* 7	5,036,049	30.07.91	Audhya, T. et al.			
	* 8	5,096,885	17.03.92	Pearlman et al.			
	* 9	5,149,653	22.09.92	Roser			
	*10	5,215,743	01.06.93	Singh, M. et al.			
	*11	5,262,296	16.11.93	Ogawa, E. et al.			
	*12	5,399,670	21.03.95	Bhattacharya, P. et al.			
	*13	5,410,025	25.04.95	Moller et al.			18.11.93
	*14	5,514,554	07.05.96	Bacus, S.			
	*15	5,571,894	05.11.96	Wels, W. et al.			
	*16	5,580,856	03.12.96	Prestrelski et al.			
	*17	5,587,458	24.12.96	King, C. et al.			
	*18	5,589,167	31.12.96	Cleland et al.			
	*19	5,608,038	04.03.97	Eibl et al.			
	20	5,725,856	10.03.98	Hudziak et al.			23.05.95
	*21	5,763,409	09.06.98	Bayol et al.			02.05.95
	*22	5,821,337	13.10.98	Carter et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No	
<i>89</i>	*23	AU-B-30771/89	07.09.89	AUSTRALIA				
	*24	2,138,853	29.06.95	CANADA				
	*25	0 531 539 A1	17.03.93	EPO				
	*26	303,746	22.02.89	EPO				
	*27	391,444	10.10.90	EPO				
	*28	597,101	18.05.94	EPO				
	*29	661,060	05.07.95	EPO (WITH ENGLISH ABSTRACT)				
	*30	841,067	13.05.98	EPO				
	*31	84/00890	15.03.84	PCT				
	*32	WO 89/09402	05.10.89	PCT (WITH ENGLISH ABSTRACT)				
	*33	WO 89/11297	30.11.89	PCT				

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P0998D1

Serial No.

09/27330

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant  
Cleland et al.Filing Date  
18 Mar 1999

Group

1642

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
8	*34	WO 90/11091	04.10.90	PCT			
	*35	WO 92/22653	23.12.92	PCT			
	*36	WO 93/05799	01.04.93	PCT			
	*37	WO 98/22136	28.05.98	PCT			

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

*38	"Sandoglobulin" <u>Physicians' Desk Reference</u> pps. 1965-1966 (1991)
*39	"IVEEGAM", "Product Information, IMMUNO U.S., Inc." pps. 2 pages (1992)
*40	Arakawa et al., "Protein-Solvent Interactions in Pharmaceutical Formulations" <u>Pharmaceutical Research</u> 14(3):737-744 (1996)
*41	Bam et al., "Stability of Protein Formulations: Investigation of Surfactant Effects by a Novel EPR Spectroscopic Technique" <u>Pharm. Res.</u> 12:2-11 (1995)
*42	Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185 <sup>HER2</sup> Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer" <u>J. Clin. Oncol.</u> 14(3):737-744 (1996)
*43	Beauvais et al., "Both Glassy State and Native Structure are Required for Storage Stability of Lyophilized Interleukin-1 Receptor Antagonist" <u>Pharm. Res.</u> (Abstract #2007) 12(9):S-80 (1995)
*44	Boulet et al., "Inhibitory Effects of an Anti-IgE Antibody E25 on Allergen-induced Early Asthmatic Response" <u>Am J Respir Crit Care Med</u> 155:1835-1840 (1997)
*45	Chang and Fischer, "Development of an Efficient Single-Step Freeze-Drying Cycle for Protein Formulations" <u>Pharm. Res.</u> 12(6):831-837 (1995)
*46	Chang et al., "Development of a Stable Freeze-dried Formulation of Recombinant Human Interleukin-1 Receptor Antagonist" <u>Pharmaceutical Research</u> 13(2):243-248 (1996)
*47	Cleland and Jones, "Development of Stable Protein Formulations for Microencapsulation in Biodegradable Polymers" <u>Proceed. Intern. Symp. Control. Rel. Bioact. Mater.</u> 22:514-515 (1995)
*48	Cleland et al., "The Development of Stable Protein Formulations: A Close Look at Protein Aggregation, Deamidation, and Oxidation" <u>Critical Reviews in Therapeutic Drug Carrier Systems</u> 10(4):307-377 (1993)
*49	Draber et al., "Stability of Monoclonal IgM Antibodies Freeze-Dried in the Presence of Trehalose" <u>Journal of Immunological Methods</u> 181(1):37-43 (1995)
*50	Fahy et al., "The Effect of an Anti-IgE Monoclonal Antibody on the Early- and Late-Phase Responses to Allergen Inhalation in Asthmatic Subjects" <u>Am J Respir Crit Care Med</u> 155:1828-1834 (1997)
*51	Izutsu et al., "The effects of additives on the stability of freeze-dried $\beta$ -galactosidase stored at elevated temperature" <u>Intl. J. Pharmaceutics</u> 71:137-146 (1991)
*52	Manning et al., "Stability of Protein Pharmaceuticals" <u>Pharm. Res.</u> 6(11):903-918 (1989)
*53	Nielsen, et al., "Stability of Freeze Dried Horseradish Peroxidase Conjugated Monoclonal Antibodies Used in Diagnostic Serology" <u>Journal of Immunoassay</u> 16(2):183-197 (1995)

Examiner

Date Considered

9/19/00

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.  
P0998D1

Serial No.  
09/273,230

**LIST OF DISCLOSURES CITED BY APPLICANT JUL 19 1999**

(Use several sheets if necessary)

Applicant  
Cleland et al.

Filing Date  
18 Mar 1999

Group  
1642

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	*59	4,891,319	02.01.90	Roser			07.05.87
	*60	5,849,700	15.12.98	Sorensen et al.			02.06.95

**OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)**

[illegible]

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark OfficeAtty Docket No.  
P0998D1Serial No.  
09/273,230Applicant  
Cleland et al.Filing Date  
18 Mar 1999Group  
1642

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

## U.S. PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Name	Class	Subclass	Filing Date
	190	4,935,341	19.06.90	Bargmann et al.			
	191	5,288,477	22.02.94	Bacus, S.			
	192	5,359,046	25.10.94	Capon et al.			
	193	5,401,638	28.03.95	Carney et al.			
	194	5,578,482	26.11.96	Lippman et al.			
	195	5,604,107	18.02.97	Carney et al.			
	196	5,663,144	02.09.97	Greene et al.			
	197	5,705,157	06.01.98	Greene			
	198	5,726,023	10.03.98	Cheever et al.			
	199	5,728,687	17.03.98	Bissery			
	200	5,801,005	01.09.98	Cheever et al.			
	201	5,837,243	17.11.98	Deo et al.			
	202	5,837,523	17.11.98	Greene et al.			
	203	5,846,538	08.12.98	Cheever et al.			
	204	5,869,445	09.02.99	Cheever et al.			
	205	5,876,712	02.03.99	Cheever et al.			
	206	5,877,305	02.03.99	Huston et al.			
	207	5,908,835	01.06.99	Bissery			
	208	5,910,486	08.01.99	Curriel et al.			
	209	5,922,845	13.07.99	Deo et al.			
	210	5,939,531	17.08.99	Wels et al.			
	211	5,977,322	02.11.99	Marks et al.			
	212	6,054,297	25.04.00	Carter et al.			
	213	6,123,939	26.09.00	Shawver et al.			

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation Yes No
	214	616,812	28.09.94	EPO			
	215	711,565	26.08.98	EPO			
	216	2,761,543B2	04.06.98	JAPAN (TRANSLATION ATTACHED)			
	217	2,895,105B2	24.05.99	JAPAN (ENGLISH ABSTRACT AND CLAIMS)			
	218	3-240498	25.10.91	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	219	5-117165	14.05.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	220	5-170667	09.07.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	221	5-213775	24.08.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			
	222	5-317084	03.12.93	JAPAN (ENGLISH ABSTRACT ATTACHED)			

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

FORM PTO-1449

U.S. Dept. of Commerce  
Patent and Trademark Office

Atty Docket No.

P0998D1

Serial No.

09/273,230

## LIST OF DISCLOSURES CITED BY APPLICANT

(Use several sheets if necessary)

Applicant

Cleland et al.

Filing Date

18 Mar 1999

Group

1642

## FOREIGN PATENT DOCUMENTS

Examiner Initials		Document Number	Date	Country	Class	Subclass	Translation	
							Yes	No
	223	7-59588	07.03.95	JAPAN (ENGLISH ABSTRACT ATTACHED)				
	224	95,006,982B2	30.01.95	JAPAN (ENGLISH ABSTRACT AND CLAIMS)				
	225	WO 92/10573	25.06.92	PCT				
	226	WO 93/12220	24.06.93	PCT				
	227	WO 93/21232	28.10.93	PCT				
	228	WO 93/21319	28.10.93	PCT				
	229	WO 94/10202	11.05.94	PCT				
	230	WO 94/28127	08.12.94	PCT				
	231	WO 95/16051	15.06.95	PCT				
	232	WO 95/17507	29.06.95	PCT				
	233	WO 95/28485	26.10.95	PCT				
	234	WO 96/18409	20.06.96	PCT				
	235	WO 96/30046	03.10.96	PCT				
	236	WO 97/27848	07.08.97	PCT				
	237	WO 97/38731	23.10.97	PCT				
	238	WO 97/45140	04.12.97	PCT				
	239	WO 98/45479	15.10.98	PCT				

## OTHER DISCLOSURES (Including Author, Title, Date, Pertinent Pages, etc.)

	240	Baselga et al., "Anti HER2 Humanized Monoclonal Antibody (Mab) Alone and in Combination with Chemotherapy Against Human Breast Carcinoma Xenografts" <u>Proceedings of ASCO-13th Annual Meeting</u> (Abstract #53), Dallas, TX 13:63 (Mar 1994)
	241	Baselga et al., "Monoclonal antibodies directed against growth factor receptors enhance the efficacy of chemotherapeutic agents" <u>Annals of Oncology</u> (abstract #010) 5(Suppl. 5) (1994)
	242	Guy et al., "Expression of the neu protooncogene in the mammary epithelium of transgenic mice induces metastatic disease" <u>Proc. Natl. Acad. Sci. USA</u> 89(22):10578-10582 (Nov 15, 1992)
	243	"Herceptin (Trastuzumab)" <u>Product Information</u> (2000)
	244	Hynes and Stern, "The biology of erbB-2/neu/HER-2 and its role in cancer" <u>Biochimica et Biophysica Acta</u> 1198(2-3):165-184 (Dec 30, 1994)
	245	Mendelsohn et al., "Receptor blockade and chemotherapy: a new approach to combination cancer therapy" <u>Annals of Oncology</u> (abstract #040) 7(Suppl. 1):22 (1996)
	246	Norton, L, "Evolving concepts in the systemic drug therapy of breast cancer" <u>Seminars in Oncology</u> 24(4 Suppl 10):S10-3-S10-10 (Aug 1997)
	247	Ravdin and Chamness, "The c-erbB-2 proto-oncogene as a prognostic and predictive marker in breast cancer: a paradigm for the development of other macromolecular markers--a review" <u>Gene</u> 159(1):19-27 (Jun 14, 1995)

Examiner

Date Considered

\*Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.